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EXAMINER

MELSON, CANDICE C

ART UNIT

PAPER NUMBER

3732

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

NK

Office Action Summary

Application No.

09/993,860

Applicant(s)

LEHUEC ET AL.

Examiner

Candice C. Melson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 16-20, 22, 23, 25-43, 46-51, 54 and 56 is/are rejected.
- 7) ☒ Claim(s) 15, 21, 24, 44, 45, 52, 53, 55 and 57 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 & 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application-by-application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Claim Objections

Claims 12 and 51 are objected to because of the following informalities: in line 1 of Claim 12 the phrase “has a three cutouts” should be “has three cutouts”. In line 4 of Claim 51, the word “vertex” should be “vertex”. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 7, 13-14, 16-17, 22, 26-27, 33-34, 37, 40, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Jobe (EP 0 867 149 A1). Jobe discloses a “bone fixation apparatus 10 for anchoring a surgical member to bone for the fixation of bone or soft tissue to bone”. “Bone fixation apparatus 10 includes a surgical plate member 12 extending across the surface of the bone and post devices 14 retaining plate member 12 in place” (column 5, lines 2-

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5). As to Claims 1 and 37, "figure 3 shows a modification of the invention where one post device 14a anchors plate member 12 to bone section 6 and two post devices 14b and 14c anchor the plate to bone section 7" (column 5, lines 19-23). These post devices are capable of being positioned through the plate into the L5 and S1 vertebrae. As to Claim 3, "figures 4 and 5 show" "flange or rib 30 depending from the posterior face 31 of the plate member 12" (column 7, lines 42-46). The posterior face 31 is capable of being positioned against the L5 and S1 vertebrae. Because the inferior margin of the L5 vertebrae is not positively claimed, this rejection also applies to Claim 34. Figure 1 shows "post devices 14" in a hole that is angled with respect to the axis extending perpendicular to the anterior face of the plate. Regarding Claims 13, 14, 17 and 27, "if additional security is desired, plate member 12 may be secured to bone by replacing one of the post devices 14, for example post device 14a shown in Figure 3, with a screw or other suitable fastener which securely engages the walls of hole 24 to attach the plate member to the surface of the bone section" (column 5, lines 29-34). As shown in Figure 1, the retaining element extends over the hole of the plate. With respect to Claim 22, 26, and 40, "although the limited engagement between the leg portion and wall of the bone is generally insufficient to securely retain the post in the hole 24, the spindle shape of leg portion 18 allows the surgeon to conveniently manipulate the surgical plate relative to the bone sections during the surgical procedure without pulling the post device from the hole 24" (column 6, lines 32-38). The spindle leg provides a means for blocking the inserted screws.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1) Claims 2,4-6,8-9,12,20,25,38,41,43,48,51,54 and 56 are rejected under 35

U.S.C. 103(a) as being unpatentable over Jobe (EP 0 867 149 A1) as applied to claims 1,14,22, and 33 above, in view of Fuentes (USPN 6,306,139 B1). Jobe discloses a plating apparatus as stated in the above-mentioned claims. Fuentes teaches an osteosynthesis or intervertebral connection device 1 adapted to be mounted on the outer surface of the cervical vertebrae” comprising “an osteosynthesis or rigid connection plate 2 adapted to cover at least partially two consecutive or contiguous vertebrae. The connection plate comprises an anterior face 5 and an opposite or posterior face 6 intended to be applied against the outer face of the vertebrae” (column 2, lines 47-55). With regard to Claims 2, 4 and 38, “the connection plate 2 presents a curvature concave along the posterior face 6” (column 2, lines 65-67). The posterior face 31 is capable of being positioned against the L5 and S1 vertebrae. Because the inferior margin of the L5 vertebrae is not positively claimed, this rejection also applies to Claim 5. As to Claim 6, Jobe discloses “the shape size and thickness of plate member 12 is subject to considerable modification depending upon the location of bone sections 6 and 7” (column 5, lines 5-8). As to Claims 8, 9 and 41, “retaining element 16 is equipped with a central ring 19 which is engaged in central hole 21 made on the connection plate” between upper and lower nodes. As to Claim 20, the ring acts as a base member from which the retaining element extends. With respect to

Claims 12 and 48, “retaining element 16 is equipped on its inner face 16a directed towards the anterior face 5 of the plate, with at least one and, for example, with four studs 42 in abutment on the anterior face 5 when the retaining element 16 occupies its position P1 of free access to the holes 8. Each stud 42 is intended to be engaged in a complementary housing 43 made from the anterior face 5 of the plate located so that the stud 42 and the housing 43 cooperate when the retaining element 16 occupies the position P2 preventing extraction of the screws” (column 5, lines 12-21). Regarding Claim 25, “As shown more precisely in FIG. 3, the ring 19 is crimped from the posterior face 6 of the plate 2. According to a preferred characteristic, the crimping effected is of the tight type, i.e. a friction appears between the retaining element 16 and the connection plate 2” (column 3, lines 29-33). As to Claim 43, as shown in FIGS. 1 and 8, the “retaining element 16” comprises “a central ring 19” for fixing to “plate 2” in either a first or second angular position “P1” and “P2” respectively. In the first position P1 the upper and lower holes are completely uncovered and in the second position P2 the upper and lower holes are all at least partially covered. With regards to Claims 51, 54 and 56, Fuentes discloses “the connection device 1 according to the invention is intended to be positioned with the aid of an instrument 30 comprising a handle 31 removably mounted on a guide block 32 designed to bear the plate 2 from its lower face with the aid, for example of clipping devices. The guide block 32 comprises a series of bores 33 made so as, in position of superposition with the osteosynthesis plate 2, to be in registry with holes 8 of the plate. In this way the block 32 makes it possible to guide, with the aid of the bores, diverse tools 34 for ensuring positioning of the plate” (column 3, lines 59-67 and column 4, line 1). It would have been obvious to incorporate the teachings Fuentes into the plate disclosed by Jobe in order to better immobilize at least two consecutive vertebrae.

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2) Claims 10, 11, 18, 19, 23, 42 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jobe as applied to claims 1 and 22 above, and further in view of Fuentes. Jobe and Fuentes disclose the apparatus as stated in Claim 9 except for the triangular and circular shaped retaining element as stated in Claims 10, 11, 23, 42 and 47. They also do not disclose the central ring and plate integrally formed. However, Fuentes discloses "retaining element 16 is equipped with a central ring 19 which is engaged in central hole 21 made on the connection plate 2" between upper and lower nodes. It would have been an obvious matter of design choice to make the retaining element with a triangular or circular shape, since such a modification would have involved mere change in the shape of a component. A change in shape is generally recognized as being within the level of ordinary skill in the art. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to integrally form the "central ring 19" with the upper face of "plate 2", since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893). As to Claim 19, "central ring 19" connects "retaining element 16" to "plate 2" in either a first or second angular position "P1" and "P2" respectively. In the first position P1 the upper and lower holes are completely uncovered and in the second position P2 the upper and lower holes are all at least partially covered. Thus, the retaining element extends around the adjacent holes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to extend the retaining elements around the adjacent holes as taught by Fuentes in order to constitute stops for the heads of the anchoring screws.

3) Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zucherman et al. (USPN 6,045,552) in view of Jobe. Zucherman et al. disclose “a spine fixation plate apparatus 50” “is particularly advantageous for use in an anterior approach to the L5, S1 vertebral region of the spine in order to immobilize the L5 vertebra with respect to the S1 vertebra”. Jobe teaches installing a generally triangular –shaped plate, which is “capable” of being positioned along the anterior face of the S1 vertebra. Jobe also teaches that three screws or “post devices 14a” may be installed in the upper and lower nodes each through a single hole in the plate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the triangular plate and screws as taught by Jobe into the method of stabilizing the L5 and S1 vertebrae as disclosed by Zucherman et al. in order to provide a suitable fastener which securely engages the walls of the holes and position these fasteners in a manner that creates a triangulation effect which substantially resists relative lateral movement of the bone sections.

4) Claims 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zucherman et al in view of Jobe as applied to Claim 28 above, in further view of Fuentes. Zucherman et al and Jobe disclose the method as stated in Claim 28 but, do not disclose installing a retaining element on the plate the block the first second and third screws, inserting a fusion device in the disc space, or coupling the plate to an instrument before installing. With respect to Claims 29 and 30, Fuentes teaches “retaining element 16 is equipped on its inner face 16a directed towards the anterior face 5 of the plate, with at least one and, for example, with four studs 42 in abutment on the anterior face 5 when the retaining element 16 occupies its position P1 of free access to the holes 8. Each stud 42 is intended to be engaged in a complementary

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housing 43 made from the anterior face 5 of the plate located so that the stud 42 and the housing 43 cooperate when the retaining element 16 occupies the position P2 preventing extraction of the screws" (column 5, lines 12-21). As to Claim 31, Zucherman et al disclose, "as can be seen in FIG. 1, a bone graft 74 has been inserted in the disk space between the L5 and S1 vertebrae. This graft is used to fuse the L5 vertebra to the S1 vertebra, while the plate immobilizes and stabilizes the L5 vertebra relative to the S1 vertebra" (column 4, lines 9-13). Finally to Claim 32, Fuentes discloses "the connection device 1 according to the invention is intended to be positioned with the aid of an instrument 30 comprising a handle 31 removably mounted on a guide block 32 designed to bear the plate 2 from its lower face with the aid, for example of clipping devices. The guide block 32 comprises a series of bores 33 made so as, in position of superposition with the osteosynthesis plate 2, to be in registry with holes 8 of the plate. In this way the block 32 makes it possible to guide, with the aid of the bores, diverse tools 34 for ensuring positioning of the plate" (column 3, lines 59-67 and column 4, line 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the teachings of Fuentes into the method disclosed by Zucherman et al and Jobe in order to provide a means of preventing extraction of the screws that is pre-fitted and can be rotated on the plate.

5) Claims 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jobe as applied to claim 33 above, and further in view of Zucherman et al. Jobe discloses the apparatus as stated in Claim 33 but, does disclose a protrusion that bears against the lower margin of the S1 vertebra. Zucherman et al disclose "a second keel 62" which "is designed to be inserted into the S1 vertebra. "Second keel could also be triangularly shaped" with a sharpened edge or ridged

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shaped similar to the "first keel 60" as shown in FIG. 1. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the keel as taught by Zucherman et al. in to the apparatus disclosed by Jobe in order to better secure the plate to the vertebrae and provide surfaces and contours for bone ingrowth.

6) Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jobe. Jobe discloses the claimed invention except for the lower holes having an oblong shape. It would have been an obvious matter of design choice to modify the holes to be oblong shaped, since such a modification would have involved a mere change in the shape of a component. A change in shape is generally recognized as being within the level of ordinary skill in the art.

7) Claims 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zucherman et al in view of Jobe. Zucherman et al disclose a system for fusion of the L5 and S1 junction of the spine. Jobe discloses a plate having a triangular shape and post devices or screws positioned through holes "capable" of securing the plate to the L5 and S1 vertebrae. Zucherman et al further discloses, "as can be seen in FIG. 1, a bone graft 74 has been inserted in the disk space between the L5 and S1 vertebrae. This graft is used to fuse the L5 vertebra to the S1 vertebra, while the plate immobilizes and stabilizes the L5 vertebra relative to the S1 vertebra" (column 4, lines 9-13). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the triangular plate as taught by Jobe into the system for fusion disclosed by Zucherman et al in order to provide a suitable fastener which securely engages the walls of the holes and position these fasteners in a manner that creates a triangulation effect which substantially resists relative lateral movement of the bone sections.

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Allowable Subject Matter

Claims 15,21,24,44-45,52-53,55, and 57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Candice C. Melson whose telephone number is (703) 305-8128. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 308-2708 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

ccm
January 24, 2003


KEVIN SHAVER
SUPERVISORY PATENT EXAMINER
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1/27/03